

# **EXHIBIT C**

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CONGRESSIONAL TRANSCRIPTS  
 Congressional Hearings  
 July 31, 2007

## Senate Judiciary Committee Holds Hearing on Oxycontin and Defective Product Liability

### LIST OF PANEL MEMBERS AND WITNESSES

LEAHY:

Good afternoon. Mr. Coburn, it's a minute too late, because we were all at our various caucuses. And I had scheduled this hearing at the request of the distinguished senior senator from Pennsylvania.

Senator Specter's long expressed an interest in criminal liability for the introduction of dangerous or defective products into the marketplace. I agree with him. This is a very important issue and one where further congressional action may be warranted.

The hearing will examine the recent plea agreement between the makers of OxyContin and the federal government. Last month, this committee held a hearing addressing the role of rogue online pharmacies and our nation's growing prescription drug abuse problem. Among young people, prescription drugs have become the second most abused drug after marijuana. Now if you exclude marijuana, more adults and teens report abusing prescription drugs than all other illicit drugs combined.

I noted then that Purdue's admitted misrepresentations about the addictive and abuse potential of their product is very troubling. The criminal conduct involved in the marketing of OxyContin has been one of the most tragic examples in recent memory of a company favoring the bottom line over the health of our nation's citizens. The tragic irony is that the dangerous product they were talking about was purported to help people manage pain.

I know that for many it has been effective. But for many others, this drug -- its diversion due to widespread distribution has caused terrible harm, from addiction to, in many instances, death. Purdue made billions of dollars marketing OxyContin as a less-addictive alternative to pain killers.

Today, we'll hear about what punishment the Justice Department found appropriate for this criminal conduct. I look forward to discussing today with the witnesses how best to prevent this type of dangerous corporate decision-making from ever occurring again. Americans should not have their lives reduced to a mere factor in an actuarial table.

While the makers of OxyContin have been prosecuted, have pled guilty, paying a multi-million-dollar fine, no one from the company is going to jail. Frankly I felt -- my days as a prosecutor, and I'm sure others like Senator Specter, who had the privilege of serving as prosecutors know -- that nothing focuses the mind as much as thinking you're going to be behind bars. Fines can sometimes become simply a cost of doing business. When you sit behind bars, you think far more about whether you did the right thing.

Now, I believe it's fair to ask in light of Purdue's profits of approximately \$2.8 billion between 1996 and 2001, whether the \$680 million in penalties they received in this plea agreement will serve as a deterrent to similar future conduct or just simply become -- well, that's part of the cost of doing business.

We'll hear testimony today about the way Purdue's conduct has affected the lives of those who have lost loved ones as a result of taking OxyContin. Many are asking why the three executives who pled guilty were not given jail time. As I said before, nothing makes corporate executives think twice about malfeasance more than the prospect of iron bars slamming shut.

The Judge who presided over the plea agreement stated at the sentencing hearing, quote, "I do not doubt that many of our fellow citizens will deem it inappropriate that no jail time is imposed. It bothers me, too." Well, I'd say to the judge, it certainly bothers me. The United States attorney who prosecuted the case will testify today about why he did not insist that the responsible corporate officials pay a similar price as the individuals who sell OxyContin on the street.

I look forward to hearing from these witnesses.

Senator Specter?

SPECTER:

Thank you, Mr. Chairman for scheduling this hearing.

The criminal charge involves a matter where there was a plea to a felony offense, including an intent to mislead. According to the DEA, in just 2000 and 2001, there were 146 deaths in which OxyContin was determined to be the direct, quote, "cause of," or, quote, "a contributing factor to," the deaths; and an additional 318 deaths that were, quote, "most likely," close quote, caused by OxyContin.

In seeing the reports on this matter with very substantial profits involved, the fine albeit substantial has a very ominous overtone of insufficient prosecution efforts. Where someone places a dangerous instrumentality in commerce with reason to believe that a death may occur, and a death does occur, that constitutes malice and support a prosecution for murder in the second degree. And I have long expressed my concern about such products in the marketplace. And that's why I suggested to Chairman Leahy that a hearing would be useful.

I believe that as a generalization, my basis on substantial experience on this committee, that there is insufficient oversight by the committee on what happens in the Department of Justice and what happens in the criminal prosecutions. I have since been contacted by attorneys representing the defendant company who contend that there's a gross misstatement of what the underlying facts are. Well, I'm prepared to listen. This committee is prepared to listen.

But Senator Leahy puts his finger on the issue. That is that there is reason to believe that it's a dangerous instrumentality, and that deaths will occur, and deaths do occur. That supports a homicide prosecution. And it's not deterred by a fine. I see fines with some frequency and think that they are expensive licenses for criminal misconduct. I don't know whether that applies in this case. But a jail sentence is a deterrent, and a fine is not -- not a corporate fine in the context of the kind of profits which are involved here.

Since this hearing was scheduled, we have a very heavy commitment this afternoon to the director of national intelligence. We have been called upon to revise the FISA law, so at least speaking for myself, I'm going to have to conclude my participation by 4 o'clock. I don't control the gavel. But the chairman...

LEAHY:

If you'll yield on that, you will control the gavel, because I'm going to be leaving before that.

SPECTER:

If I control the gavel, the hearing will be over by 4 o'clock.

LEAHY:

And I'm going to turn the gavel over to you.

SPECTER:

Well, we have the time limits of five minutes. And if I had the gavel, I would request -- in fact, even if I didn't have the gavel, I'd request the witnesses stay within the time limits to give the maximum time for dialogue. But we have enough time to give this a thorough hearing.

I had a call from Senator Coburn who was concerned about the adequacy of the witness list. And I immediately said the witnesses he wanted to add I thought were fine. And we have an expert here. We have a couple of experts: one in the medical field and one in the legal field. So we'll see how it goes.

Thank you, Mr. Chairman.

LEAHY:

Thank you.

Mr. Brownlee, would you please stand and raise your right hand? Do you solemnly swear the testimony you will give is going to be the truth, the whole truth and nothing but the truth, so help you God?

BROWNLEE:

Yes, sir.

LEAHY:

Thank you.

COBURN:

Mr. Chairman, might I have the privilege of having an opening statement?

LEAHY:

Certainly.

COBURN:

First of all, what has happened with OxyContin in terms of how it's been abused represents some of the greatest problems we have in this country with polydrug abuse. As a practicing physician, as a cancer survivor, as somebody who has prescribed this medicine, I'm somewhat concerned with the direction we're taking.

And the question I would ask of the chairman and the ranking member is where's our study on Lortab and the drug and polydrug abuse with Lortab? Where's our study and our hearing on Coumadin and the people that die every year from Coumadin?

The facts are that 98 percent of the people who died using this drug are polydrug abusers. Now, whether there was intent to distribute outside of there -- but I think it's really important that everybody recognizes what a class II drug is. It's a highly addictive drug. And where's the question as the culpability on the medical community in this country who wrote the prescriptions for this drug? They read the PDR. They read the approved statement, which fully outlines the dangerousness of this drug when used in an inappropriate manner.

The thing that concerns me, never was it alleged that this drug was designed to be ground up and used in an illegal fashion, and that there was a motivation to do that. And yet we're coming after a drug manufacturer who may or may not, according to the plea, has pled guilty to

something. But we're turning a blind eye to all the other areas. The problem in this country is polydrug abuse. Ninety-eight percent of the people who have died with this on autopsy are found to have multiple other drugs.

Look at the other side of it. Look at somebody who has bone pain from metastatic bone cancer and say do we not want them to have this wonderful drug that makes like bearable instead of unbearable? We're not considering this in a balance fashion. And I believe, as a physician, number one, I ought to challenge my own profession. They created this problem by not following their own ethical standards, and by writing prescriptions for drugs that they never should have written. And the same thing's going on with Lortab right now.

Final point -- we need to be careful that we don't act as the FDA. This was an approved drug, under Schedule II that everybody in the medical community understands the addictive potential and the danger of. And to say and to hold no culpability for the physician community, I think, would be seriously in error.

And I thank the chairman for allowing an opening statement.

LEAHY:

Thank you.

Mr. Brownlee, I expect that you're aware that your name appeared on at least one termination list of U.S. attorneys. The Washington Post reported this list was prepared in November 2006 by Mike Elston, who was the chief of staff of then-outgoing Deputy Attorney General McNulty.

Why do you think Mr. Elston put you on that list?

BROWNLEE:

Well, Mr. Chairman, first of all, thank you for allowing me to be here today to testify. I do not...

LEAHY:

I'm glad you are here. As I told you before we started, as a prosecutor, you have probably the best job in America. Go ahead.

BROWNLEE:

Thank you, sir. I do not have specific knowledge of exactly why Mr. Elston placed me on that list. No one has come forward and told me. However, when I learned that I had been placed on the list, Mr. Elston is the one who informed me on March 14 of this year, I became concerned enough that I reported that event to the Justice Department that very evening. And so, although I don't have any conclusive information as to why I was targeted for termination, I certainly had concerns about it and reported that.

LEAHY:

Did you discuss it with Deputy Attorney General McNulty?

BROWNLEE:

I spoke to Mr. McNulty the following day, on March 15. I told him that my name had appeared on his list by Mr. Elston in an e-mail dated November 1, 2006; that I was concerned about it. And I outlined him the facts that I knew concerning that. He assured me that Mr. Elston was a good man. I had my own views of that.

LEAHY:

Had you ever been given any negative evaluations by Mr. Elston or by anybody at the department?

BROWNLEE:

No, sir.

LEAHY:

I find this interesting, because you have such an interesting background. I'm surprised you're on there. I realize I overlooked giving you time for an opening statement, which I will. I was just going to ask you two other questions. And I'll stop with that.

In your written testimony, you say you began your investigation of Purdue's activities regarding OxyContin in the fall of 2001.

BROWNLEE:

That's correct.

LEAHY:

You then spoke with officials at Maine Justice, including Mr. Comey about the charges you're considering. Were you given any direction or criticism or pressure from anyone in the Justice Department with regard to your investigation or your plea negotiations?

BROWNLEE:

If I may split that into two answers. I spoke to Mr. Comey in 2005 concerning an issue regarding our application of the Thompson memo which was in effect at the time that we were investigating this case. Mr. Comey had received information from defense counsel that the Western District was not applying that pursuant to DOJ policy.

So Mr. Comey inquired. I felt the inquiry was serious enough that I actually grabbed one of my -- not grabbed -- but one of my prosecutors and I drove up to Washington to Roanoke and sat down with Mr. Comey and laid out for him exactly what we had done pursuant to Thompson; our methods for trying to acquire the necessary records to do this investigation. Once Mr. Comey heard my explanation, he said, "Brownlee, you're fine. Go back to Virginia and do your case." And we did. And I never spoke to him about the matter.

LEAHY:

Did you ever get any pressure from anybody else, even after Mr. Comey left?

BROWNLEE:

The only thing that ever occurred was from Mr. Elston himself on October 24, I believe, 2006. That's the day that this plea was to expire. We had provided counsel for the company on October 19, I believe, the final government offer to settle this case, or they would face other things. And so that evening -- we had received earlier that day authority from the Justice Department to go ahead and accept the plea or charge the company.

Mr. Elston, who I had only met on one prior occasion on August 3 -- so I'd only known him less than 90 days -- contacted me and was inquiring about the case. He told me he had received a phone call from one of the defense lawyers about the case, and that that counsel had once again said that we were moving too quickly, that they needed more time -- those kinds of things. And through his questioning of me, I sensed that he was inquiring almost on their behalf. I asked him if he was calling on behalf of the deputy attorney general. And I was at home at this time. He told me he was not.

Once I learned that he was not speaking on behalf of Mr. McNulty, based on the fact he had never attended any substantive briefings, and he was one that I did not feel understood the case, I

simply just kind of dismissed him and told him that I had authority from Mrs. Fisher (ph) to proceed forward. And we were going to do just that. And he needed to back out of the way of the case. And ultimately he complied with that. And the company accepted the plea that evening.

LEAHY:

Thank you. And please feel free to go ahead and give your opening statement. I apologize. Sometimes I forget the procedure here, being new at this job.

Go ahead, give your opening statement, Mr. Brownlee.

BROWNLEE:

Chairman Leahy, Senator Specter, and members of the committee, thank you for holding this hearing and allowing me the opportunity to testify.

During the past five years, I led a team of career prosecutors from my office and the Department of Justice as well as state and federal investigators that conducted a sweeping investigation of the manufacture and distributor of the painkiller OxyContin. Bringing this company and its executives to justice was a difficult and important challenge. And I'm grateful for the hard work of the law enforcement professionals on whom these convictions rest. They represent the very best of our nation's law enforcement. And I'm honored to serve with them.

According to the evidence, Purdue began using focus groups of primary care physicians in 1995 to determine whether such physicians would be willing to prescribe OxyContin for patients with non-cancer pain. These focus groups showed that what doctors wanted was a long-lasting pain reliever that was less addictive and less subject to abuse and diversion. Purdue understood that the company that marketed and sold that drug would dominate the pain management market. And that is exactly what Purdue set out to do.

Despite knowing that OxyContin had an abuse potential similar to that of Morphine and was at least as addictive as other pain medications on the market, in January of '96, Purdue began marketing OxyContin as less addictive, less subject to abuse and diversion and less likely to cause tolerance and withdrawal than other pain medications. Due in part to Purdue's aggressive and misleading marketing campaign, prescriptions for OxyContin skyrocketed, increasing from approximately 300,000 in 1996 to nearly 6 million in 2001. As OxyContin became more available, its abuse and diversion increased. And this increase had devastating effect on many communities through Virginia and America.

On May 10, 2007, Purdue pleaded guilty to a felony charge of illegally misbranding OxyContin in an effort to mislead and defraud physicians and agreed to pay \$600 million, an amount that represented approximately 90 percent of the profits for the sale of OxyContin during the time period of the offense. Purdue also was required to subject itself to independent monitoring.

In addition, Purdue's president, Michael Friedman; general counsel, Howard Udell; and former chief medical officer, Paul Goldenheim pled guilty to a misdemeanor charge of misbranding OxyContin. These defendants were placed on supervised probation for three years, ordered to perform 400 hours of community service, and collectively paid \$34.5 million in criminal fines.

Like other high-profile prosecutions, this case has not been free of controversy. It has been suggested that my office attempted to demonize OxyContin, and that our decision to charge the executive was, quote, "a regrettable choice of prosecutorial discretion," end quote. On the other hand, our decision not to seek active incarceration also has been questioned.

After studying this case and the evidence carefully, I am confident that the facts and law compelled our decision to prosecute and sentence this company and its executives in precisely the manner in which we did. The three executives pled guilty to a strict liability misdemeanor offense based on the fact that they would be responsible corporate officers of this pharmaceutical company. This misdemeanor charge required no proof of intent or actual knowledge of the violations to establish their guilt.

The intent of the statute is to impose the highest standard of care on certain corporate officials. The three defendants had no prior criminal records. And the sentencing guideline range for each defendant was zero to six months.

Under these circumstances, I decided, and the court has agreed, that prison sentences were not necessary to adequately punish these defendants. Convictions of the corporate officials will have significant consequences. Each defendant will bear the stigma of being a convicted criminal. These convictions also will send a strong warning to executives of other pharmaceutical companies that they too will be expected to exercise the highest standard of care.

During the last several years, I have spoken to many people who have been harmed, or who have had a loved one harmed by OxyContin. People like Marianne Skolek, whose daughter, Jill, died from OxyContin, and whose grandson, Brian, will now grow up without his mom. My belief is that these convictions have advanced the cause of justice and, I hope, offer some measure of closure for those who have suffered. These convictions have confirmed what many believed for a long time -- that Purdue's marketing of OxyContin was deceptive and criminal.

It is important to note that most of the people never claimed that Purdue was solely responsible for their loved ones' death. They just wanted Purdue to tell the truth about the drug. The investigators and prosecutors who built this case have brought that truth to light.

On April 1, 1940, Attorney General Robert Jackson spoke to a group of United States attorneys who had assembled in the great hall at Maine Justice. The future Supreme Court justice reminded those federal prosecutors of their ethical and legal duties in pursuing justice; and I quote, "What every prosecutor is practically required to do is to select the cases for prosecution, and to select those in which the offense is the most flagrant, the public harm the greatest, and the proof the most certain," end quote.

I am confident that our prosecution of Purdue and its executives and the sanctions imposed are consistent with department policies and Robert Jackson's mandate for justice.

I thank the committee for allowing me to appear before you today. And I would be pleased to answer your questions. Thank you, sir.

LEAHY:

Well, thank you very much, Mr. Brownlee. And I must state that I'm very pleased to have you here not only publicly, but privately before. You should know I appreciate your duties in the Judge Advocate's court in the Army Reserve.

BROWNLEE:

Thank you, sir.

LEAHY:

Probably a little bit different than your days as a paratrooper. But...

BROWNLEE:

Yes, sir. Thanks.

LEAHY:

And some days that may look like it's more enjoyable.

BROWNLEE:

Some days jumping out of a plane looks pretty good, Senator. Thank you.

LEAHY:

I've done it once for the Golden Knights. And I would do it again in a second. And I hope my wife didn't hear me say that, because there would be probably a vote on that.

I turn the gavel over to Senator Specter.

SPECTER:

Thank you very much, Mr. Chairman.

Mr. Brownlee.

BROWNLEE:

Yes, sir.

SPECTER:

The company pled to a felony offense, including an intent to mislead.

BROWNLEE:

That's correct.

SPECTER:

Chief Judge Jones said, quote, "In the absence of legal proof of the government that the individual defendants had knowledge of the wrongdoing charged or participated in it, I do not think prison appropriate," close quote.

Didn't the government establish the underlying facts of the guilty plea, that there was intent to mislead known to the individual defendants?

BROWNLEE:

The answer is no, sir. The way we built this case was through -- in December of 2002, we served an administrative health care subpoena on the company, a multi-page document requesting records concerning the marketing of OxyContin. Once we got those records, conducted hundreds of interviews -- these were millions of documents. We put them in a database. And the investigators and prosecutors, through word search programs, went through those records and built a case against the company.

It was almost putting together a puzzle. It was a piece from a training manual. It was a piece from a call note.

SPECTER:

You ended up with an indictment that the corporation and the individual defendants -- corporation doesn't act by itself. Corporation acts through individuals who become individual defendants. But they had an intent to mislead.

BROWNLEE:

That's correct.

SPECTER:

And that resulted in, caused, a great many deaths.

BROWNLEE:

Yes, sir.

SPECTER:

Well, that being so, wasn't there legal proof that the individual defendants knew -- since they intended to mislead -- knew what they were doing?

BROWNLEE:

Well, the evidence that we submitted to the court under the agreed statement of facts did not include that. And I want to be very careful, Senator Specter, on how I speak concerning facts. Much of these facts are protected under Rule 6(e). And so this was a grand jury...

SPECTER:

It wasn't presented to the court. Does that mean you didn't have the facts? You did make the charge of intent to mislead.

BROWNLEE:

We did as to the corporate entity. This was a corporate culture put together by many people.

SPECTER:

Well, I understand. I understand that.

BROWNLEE:

Yes, sir.

SPECTER:

But the corporation doesn't act by itself. It's inanimate. It acts through people. So are you saying you couldn't identify the people?

BROWNLEE:

I think it's fair to say that, when we looked at the proof as to the corporate entity, and we looked at the proof as to particular individuals, that proof tested out differently. As you well know, that a corporation can be held criminally responsible for the acts of its agents. For instance, if a sales representative in another...

SPECTER:

I understand that.

BROWNLEE:

Yes, sir.

SPECTER:

It could only be held liable for the acts of its agents. That's the way it's liable. And it could only be held liable for intent to mislead, if its agents intended to mislead.

BROWNLEE:

Yes, sir.

SPECTER:

But once you have agents who intend to mislead, you have the requisite proof to charge them with wrongdoing...

BROWNLEE:

Right.

SPECTER:

... which the judge said that he didn't have. There's a total disconnect. Either you have the basis for saying that there's an intent to mislead, or you don't. And if you have a basis for saying there's an intent to mislead, it's because individuals acted in a way which led you to that conclusion. And that being so, I do not see how you can have a conclusion that the individuals weren't wrongdoers who deserved jail.

BROWNLEE:

Well, Senator Specter, I think that the way it boils down is that -- I mean, the premise, I believe, is correct. But when prosecutors and investigators look at particular evidence as to a particular individual, the outcome may very well be different.

For instance, in the example, let's say that that sales rep did go to a physician and provide misleading information about the product. There may be a sense well, maybe you can prosecute that particular individual based on that statement. But then you look behind it, and the defense would be well, wait a minute. I was trained that way. And look at the training manual. It has a graph in there that tells me this. And then...

SPECTER:

If you were trained that way, they didn't intend to mislead. Unless they knew that they were misleading, they didn't intend to mislead.

BROWNLEE:

Exactly.

SPECTER:

Once you have them intending to mislead, you have them engaged in conduct which merits jail.

BROWNLEE:

Well, I think that the senator's correct in the sense that under that scenario, that individual would not -- we could not prove that that individual had the intent to mislead. But as a corporate entity...

SPECTER:

Well, could you prove that any individual had the intent to mislead?

BROWNLEE:

We did not charge any individuals with the intent to mislead.

SPECTER:

I understand you didn't charge them.

BROWNLEE:

Right.

SPECTER:

That's wasn't my question.

BROWNLEE:

Yes, sir.

SPECTER:

My question was couldn't you prove that some individual had an intent to mislead?

BROWNLEE:

The evidence in this case was reviewed by career prosecutors and investigators. And it was their judgment, and I agree with them, that under the evidence in this case, that the charging decisions, the felony for the company and the strict liability misdemeanors for the executives were the appropriate charging decisions. I must tell you, this case -- no one wanted to bring these defendants to justice more than the Western District of Virginia.

We initiated this in 2001. We spent four years going through millions of records, conducting hundreds of interviews. And this is the evidence of the case. And the career prosecutors who have gone through this have asked themselves -- we asked ourselves the very questions you're asking me practically every day for years about this case. We are bound by the policies of the department.

The Ashcroft says: You must charge the most serious, readily provable charge that the prosecutor has a good-faith belief that he or she can prevail at court; which means a lawyer would have to stand up and prove, beyond a reasonable doubt to unanimous verdict that a particular individual had the specific intent to mislead. And after reviewing this evidence, the charges that we came up with were the appropriate charges with this evidence.

SPECTER:

Well, the red light went on on our last exchange. And I believe in observing the time limits meticulously, because I'm asking everybody else to. But I do not agree with you.

The famous Thompson memo, Deputy Attorney General Larry Thompson, quote, "Prosecution of a corporation is not a substitution for the prosecution of criminally culpable individuals within or without the corporation," close quote.

And where you have a basis for saying that there was intent to mislead by an individual, well, that's enough. And I respect your professionalism, and I respect your judgment. But speaking from an oversight capacity...

BROWNLEE:

Yes, sir.

SPECTER:

... I disagree.

BROWNLEE:

Yes, sir.

SPECTER:

Senator Cardin.

CARDIN:

Thank you very much, Mr. Chairman.

Mr. Brownlee, welcome to the committee.

BROWNLEE:

Thank you, Senator.

CARDIN:

You're in a difficult position. It doesn't look like you can win on either side on this issue. But I first want to compliment you for bringing this case.

BROWNLEE:

Thank you, Senator.

CARDIN:

For challenging the corporate structure and doing a professional investigation, which was extremely difficult to establish a case of criminal conduct; and then presenting it in a way that you could succeed in court. It is challenging. And there are a lot easier cases that you could have worked on. But you chose an extremely difficult case. And I think it will have a major impact on corporate conduct in our country.

BROWNLEE:

Yes, sir.

CARDIN:

Now having said that, I think the point that Senator Specter is raising is a legitimate point. When we saw corporate greed hurt shareholders and employees, the Congress changed its laws. Sarbanes-Oxley was passed. And we changed the attitude that it's all right for corporations and businesses to do whatever they wanted to do; that Congress would take a more aggressive role.

And I'm just wondering whether we have a similar problem here. I think the point that Senator Specter raised about a company that is guilty of intentional conduct, misrepresenting information that leads to consumers being put at risk and losing their lives -- that type of criminal conduct is actionable by more than just fines. And yes, it's extremely difficult to be able to prove the actions of the agents. But somebody in this company is responsible for intentionally taking action that put the public at risk and cost people their lives.

So I'm just wondering whether there's a need for change of law or other types of tools that can be made available; because I do think there's dual standards in America in our criminal justice system, that if you happen to be guilty of traditional type crimes, we wouldn't think twice about letting you out of jail. You're going to go to jail. But if you have a sophisticated network in which people are killed, you can avoid jail time. To me, that's something that's unacceptable in our system. And we need to look for how we change policy.

And I want to thank Senator Coburn for his point, because I think there is responsibility beyond just the pharmaceutical company here. People in the medical community, who perhaps look for easy ways to deal with a problem and do not supervise properly or find out the medical history of an individual in prescribing certain medications, are also at least negligent if not further than negligent.

So I think this case brings up the need for further review by perhaps Congress and by prosecutors as to whether we can't have a more effective way to get the message out that our system of justice is going to be equally applied. And people who intentionally bring harm to other people are going to pay the consequences and not just the fine.

BROWNLEE:

Thank you, Senator.

CARDIN:

That's more of a statement, I guess, than a question. But I really do want to come back to the point. This was not an easy case.

BROWNLEE:

Thank you, Senator.

CARDIN:

And I admire your willingness to take this on. And I hope that the questioning you hear today is not interpreted as challenging the manner in which you proceeded. But we need to learn from this experience to make sure that those that are responsible for criminal conduct are held accountable in our system.

Thank you, Mr. Chairman.

BROWNLEE:

Thank you.

SPECTER:

Thank you, Senator Cardin.

Senator Coburn?

COBURN:

Mr. Brownlee, I too want to compliment you for your service, one.

BROWNLEE:

Thank you, Senator.

COBURN:

It's extremely frustrating to be a physician in this country today and see all the problems we have in terms of access to care, lack of availability of drugs, drugs being used inappropriately. So looking at the problem that you had -- I don't find any fault with what you did. But I have some questions that I'd just like to have answered for me.

BROWNLEE:

Yes, sir.

COBURN:

As you looked at all this documentation, did you see a systematic marketing plan in all areas of the country that was designed to oversell this product and under-represent its risk?

BROWNLEE:

I believe the evidence that was submitted to the court established the fact that the company, as a corporate entity, made a judgment that they were going to market this drug in a way that -- and told doctors essentially that the basic premise is addicts wouldn't like it. There was a graph that they used.

COBURN:

But that was throughout the country. You didn't see different areas throughout different areas of the country where you saw more penetration and less penetration; where you saw somebody doing this to a great extent than other areas. And the question I asked you was, was there a marketing plan that you actually saw that said that this was an intent to do this?

BROWNLEE:

Again, I think the evidence that was submitted certainly indicated that the company intentionally marketed the drug that it would be less addictive, less subject to abuse and diversion. And that was the evidence that's been submitted to the court. As far as all parts of the country, I mean, it was a company that certainly marketed the drug in all areas of the country. And so yes, that marketing was for everyone.

Now, some sales reps pushed harder than others. Some sales reps said different things. But you had a training manual that had these graphs in it. And I believe that -- and some other pieces of marketing, that was company-wide. And so...

COBURN:

Well, if that's the case, and these executives were responsible for that marketing plan...

BROWNLEE:

Yes, sir.

COBURN:

Why are they not culpable along the lines that Senator Specter asked you?

BROWNLEE:

Well, I would say, first of all, that they have been held accountable as far as...

COBURN:

But in light of his question.

BROWNLEE:

Right.

COBURN:

In other words, you didn't feel like you had the proof to convince a jury 100 percent that that was the case.

BROWNLEE:

That's correct. We looked at this evidence very carefully for a long period of time. It was our judgment that the charges that we brought -- the felony for the corporate entity, the strict liability misdemeanor for the executives -- was sufficient -- well, was appropriate under the evidence that we gathered.

COBURN:

So let me ask you another question.

BROWNLEE:

Yes, sir.

COBURN:

Why were the guys that were out doing this and violating what they knew this said, which is the label...

BROWNLEE:

That's right.

COBURN:

Why weren't they prosecuted?

BROWNLEE:

I answer that in two ways. First of all, the proof as to a particular individual, as we reviewed it, was difficult to establish beyond a reasonable doubt. As I gave the example to Senator Specter, there were some good defenses that, because the corporation had training manuals, they had marketing materials, they had videos in which they were trained this way.

COBURN:

But Mr. Brownlee.

BROWNLEE:

Yes, Senator.

COBURN:

These are professional sales representatives. The one thing they're taught everywhere in the country is the label's what counts. And you can't go beyond the label. They all know that. So whether they were trained to do it or not, they're also trained that you cannot go beyond the label. So the question comes, if you don't have proof that the individual sales reps were actually doing it, and you don't have proof that will convince a jury that the executives were, how do you know they were?

BROWNLEE:

Well, I think...

COBURN:

And I'm not disputing your case.

BROWNLEE:

Right.

COBURN:

I've said that. But how do you know they were?

BROWNLEE:

Well, in this case, they pled guilty, so they told us they were. So in that sense, they've admitted it. But it's a valid question. How could we have established at trial that this company committed a felony? It's my judgment if you look at all the pieces of that puzzle, and you put it together, I would feel comfortable, as a litigator standing in front of a jury and making the point, this was a corporate culture.

This was a company. Look at the training manual. Look at these call notes. Look at these statements here. And you put it together. I may not equal individual culpability as to a particular person. But as a whole, I felt comfortable arguing before a jury that we had sufficient evidence to convict the corporate entity.

This was a case where there wasn't that smoking gun. There wasn't that aha moment where we found the e-mail that had the grand admission. It just wasn't that kind of case. It was kind of a deliberate process. And it's one of the reasons why it took so long to build that kind of case.

COBURN:

You've become pretty familiar with this drug, right? I mean...

BROWNLEE:

I've never taken it, but...

COBURN:

No, no. I'm not accusing you of that. Hopefully you won't ever have to take it.

BROWNLEE:

Yes, sir.

COBURN:

When taken properly, it's a very good drug. The question I have for you is, if you had a significant pain problem today, and your doctor offered you OxyContin, because that's the best way to treat it, would you be afraid to take this drug?

BROWNLEE:

Senator, it's hard to say what I would personally do.

COBURN:

Well, let me rephrase it a different way then. If I offered you three Lortab instead of an OxyContin 10, would you take that?

BROWNLEE:

Again, sir. I've been very blessed. And I'm not sure what a Lortab does either.

COBURN:

Well, it's oxycodone.

BROWNLEE:

OK.

COBURN:

Except it's not in a slow release. So here's the point I'm trying to make.

BROWNLEE:

Yes, sir.

COBURN:

We're talking about a drug that I personally have experience with as a physician -- and hundreds of thousands of other physicians do too -- that shows that it does a very good job. The problem is the abuse potential of it. So the one point I want to make clear in here is there is a great value to this medicine for me as a practitioner and thousands and thousands of other doctors.

SPECTER:

Senator Coburn, how much more time will you need?

COBURN:

I'll stop with that if we're coming back again. Are we coming back again? I guess the point I want to make is this isn't about the drug.

BROWNLEE:

Absolutely.

COBURN:

This is about the actions. And I want to make sure we keep it separate, because if we do to all the other abuse potential drugs -- all the other class II drugs -- if in fact there's anything out there in terms of the marketing, what we've done here, I may be without the kind of drugs that I need for patients in the future. So we need to separate the issue.

BROWNLEE:

Yes, Senator.

COBURN:

And this has value in terms of this drug does have great value. It's also a very dangerous drug. And all narcotics are highly susceptible to abuse.

BROWNLEE:

If I may respond just on one issue. You are absolutely correct. And we were very careful to build this criminal case about the specific facts of the misrepresentation, the misbranding. And that's within the agreed statement of facts. And that's what provides the factual basis for the plea.

But I also believe, as I talked about in my press release and press statement, and the court talked about in his order, that there was significant harm caused by the misbranding of the drug. So much of it got out there, that it gave addicts and those dependent and others the opportunity to abuse it.

So you're absolutely right, sir, that when we're in the courtroom conducting a Rule 11 colloquy, it's the facts that support the plea. But as Chief Judge Jones noted in his order, there was harm caused by this. And a lot of folks suffered. And it's one of the reasons why we pursued it as we did, because of that harm.

COBURN:

Well, my only concern is we should have been pursuing every physician who was writing a script for it when it wasn't needed. And that's the defect on the side of the Justice Department, the DEA. Doctors make millions of dollars writing this drug when they shouldn't be doing it. And we're not putting them in jail. And they need to be in jail for that, because they're just as guilty as anybody in that company who might have marketed it wrong.

BROWNLEE:

I will say that my office -- and I can't speak for the entire department. And we have 23 federal prosecutors, so we're a pretty small shop. But we have taken an aggressive stance against physicians as well. We have prosecuted physicians. We recently convicted a physician out of Nevada who was -- I think it was an Ob/Gyn -- who was prescribing OxyContin to folks from Southwest Virginia. They were actually driving to Nevada and getting the scripts and coming back. And then selling them and taking them. So we reached out to Nevada and convicted them.

SPECTER:

Thank you, Senator Coburn.

Senator Sessions?

SESSIONS:

Thank you. I don't why I thought about a case I prosecuted. It was a Fortune 500 case -- and defendant, formerly a Fortune 500 company. And it was so complicated. It had one of the best prosecutors in America involved in it, and had one of the best defense lawyers -- several great defense lawyers. And so we finally got a misdemeanor charge on one of the guys. And he's a professional lawyer.

He said well, we'll tell you what you really want to know (inaudible). Large amounts of money going through a foreign consulate and all kinds of things -- it was great of interest to us. And he pled and testified. And we convicted the top guy for perjury and that sort of thing. And we got to court. And the judge chewed me out. He thought we'd given too sweet a deal to the guy who pled guilty to get the other guys.

I mean, we never would have had a case. I mean, you have to work cases in difficult ways. It was an intense effort.

But first of all, with 24 assistants, you have a number of those on civil matters, a number of those on training matters, a number of those -- so you don't have that many line prosecutors, do you? It's a fairly small office compared to the several hundred some of the big offices have.

BROWNLEE:

We are fairly small. Of those 23, four are civil, 19 handle criminal work over three staffed offices, and then the U.S. attorney...

SESSIONS:

You have three different offices. Well let me just -- were you personally involved in this case? Did you work it?

BROWNLEE:

From the very beginning to the end.

SESSIONS:

Well, that's unusual. A lot of the prosecutors just sit upstairs and let the assistants do all the work. So I congratulate you on that. Are you aware of any U.S. attorney in recent years who's got a \$600 million fine against a company?

BROWNLEE:

Gosh, Senator, I'm sure someone out there's done better than me. But again, I'm not aware of that this year.

SESSIONS:

That's one of the biggest fines I've observed. And first, I just want to say that to you.

BROWNLEE:

Thank you, Senator.

SESSIONS:

First of all, you personally led this case. It could have been prosecuted in any district in America, I suppose.

BROWNLEE:

Yes, sir.

SESSIONS:

You stepped up. You led the fight. You really crushed their defense ultimately. And I am sure, with this much at stake, they had some of the best lawyers in America involved in defending the case. And you got pleas on two of the top CEOs and \$600 million fine on the corporation. And 90 percent of the profit off of this drug -- Senator Coburn makes a valid point - - it dawned on me. A lot of this drug was legitimately sold. It is not in itself inherently an evil drug. So you got 90 percent of the profit. That means you got far more than the abused sales that occurred. I want to make that point.

Secondly, we created -- Congress did at some point in its history -- a strict liability statute. And that means -- I'll summarize it and see if it's correct -- that you simply prove that they ran the red light, that they violated the standards. And you don't have to show any criminal intent.

BROWNLEE:

That's correct.

SESSIONS:

You're just guilty. Is that correct?

BROWNLEE:

That's correct. We just have to establish that they were the responsible corporate officers of a particular company that delivers products under the Food, Drug and Cosmetic Act.

SESSIONS:

But to convict them of felony, you have to have a specific criminal intent.

BROWNLEE:

Yes, sir.

SESSIONS:

And you had to prove it as to each one of the persons you had individually charged. Is that correct?

BROWNLEE:

That's correct, Senator.

SESSIONS:

Now, with regard to prosecuting a corporation, you can aggregate knowledge, can you not? In other words, you can prove this option knew this. This one knew that. This one knew this. And as a whole, the corporation was acting unlawfully. And you can sue the corporation. It's not an entity. It doesn't have the same constitutional rights that individuals have.

BROWNLEE:

That's correct. I mean, it would obviously have a trial, if it went there, and have all its rights in many ways. Although I'm not so sure they actually have grand jury protection. I think that's

still a debatable issue. But you do aggregate, or you do look at, the actions of all the players, all its agents, when assessing corporate liability. And that's what we've done.

SESSIONS:

And whereas it may not be enough to prove personal criminal intent, felony knowledge, on an individual, that information can be aggregated as proof that the corporation as a whole had knowledge. And the corporation can be held liable.

BROWNLEE:

That is correct.

SESSIONS:

And that's what you did on the corporation.

BROWNLEE:

That's what we've done on the corporation.

SESSIONS:

Now, you did not -- to convict the officers of a felony -- and we've got several libertarians on this committee that think you can't prosecute terrorists, you know. They want to give them every right in the world. But anybody that's a -- I shouldn't say that. Let me withdraw that. That's not a fair statement.

We do have a great deal of interest in seeing that even terrorists have a fair shake and the law is properly applied. But I guess what I'm saying with regard now to those individual defendants, you have to prove, to charge them with a felony, that they had specific knowledge of the standards that were expected of them; and that these standards were not being adhered to; and that they authorized them in some fashion. Is that correct?

BROWNLEE:

The government would have had to establish, beyond a reasonable doubt, that whichever particular individual you charged had the intent, and showed the intent, to defraud or mislead.